

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and  
EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN  
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**JOINT STIPULATION REGARDING CLAIM CONSTRUCTION**

Plaintiff Gilead Sciences, Inc.<sup>1</sup> and Defendants Mylan Inc. and Mylan Pharmaceuticals, Inc. hereby stipulate to the following claim constructions.

**I. U.S. Patent No. 8,592,397**

<b>TERM/PHRASE</b>	<b>STIPULATED CONSTRUCTION</b>
“fixed dose combination”	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient
“pharmaceutical dosage form”	a pharmaceutical dosage form for human administration
“less than [10%/5%] degradation of the tenofovir disoproxil fumarate or emtricitabine after 6 months”	less than [10%/5%] degradation of one or both of the TDF or FTC after 6 months
“degradation”	loss in % label strength
“dosage form is oral”	an oral dosage form for human administration
“less than 1% of impurities related to tenofovir disoproxil fumarate and	less than 1% of impurities related to each of TDF and FTC

<sup>1</sup> Plaintiff Gilead Sciences, Inc. is the owner of the U.S. Patent Nos. 8,592,397 and 8,716,264 (“the ‘397 and ‘264 patents”). Co-plaintiff Emory does not own, and has no interest in, the ‘397 and ‘264 patents.

TERM/PHRASE	STIPULATED CONSTRUCTION
emtricitabine”	

**II. U.S. Patent No. 8,716,264**

TERM/PHRASE	STIPULATED CONSTRUCTION
“fixed-dose combination”	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient
“less than [10%/5%] degradation of the tenofovir disoproxil fumarate and emtricitabine after six months”	less than [10%/5%] degradation of each of the TDF and FTC after 6 months
“degradation”	loss in % label strength
“40° C./70% relative humidity”	40° C./75% relative humidity
“pharmaceutical dosage form”	a pharmaceutical dosage form for human administration
“dosage form is oral”	an oral dosage form for human administration

STIPULATED and AGREED to this 19<sup>th</sup> day of February, 2015.

/s/William J. O'Brien

Thomas Krzeminski (*pro hac vice*)

thomas.krzeminski@knobbe.com

William O. Adams (*pro hac vice*)

william.adams@knobbe.com

Karen Cassidy (*pro hac vice*)

karen.cassidy@knobbe.com

**KNOBBE, MARTENS, OLSON & BEAR, LLP**

2040 Main Street, 14th Floor

Irvine, CA 92614

Telephone: (949) 760-0404

Facsimile: (949) 760-9502

William R. Zimmerman (*pro hac vice*)

bill.zimmerman@knobbe.com

Jay R. Deshmukh (*pro hac vice*)

jay.deshmukh@knobbe.com

Christopher C. Kennedy (*pro hac vice*)

chris.kennedy@knobbe.com

/s/Chad L. Taylor

Colleen Tracy (CT 8377)

MAYER BROWN LLP

1675 Broadway

New York, NY 10019

David B. Bassett (DB 8727)

WILMER CUTLER PICKERING HALE

AND DORR LLP

7 World Trade Center

250 Greenwich Street

New York, NY 10007

Christopher Borello (CB 6164)

FITZPATRICK, CELLA, HARPER

& SCINTO

1290 Avenue of the Americas

New York, NY 10104

**KNOBBE, MARTENS, OLSON & BEAR, LLP**

1717 Pennsylvania Avenue, NW, Suite 900  
Washington, DC 20006  
Telephone: (202) 640-6400  
Facsimile: (202) 640-6401

*Local Counsel:*

Gordon H. Copland (WV Bar #828)  
gordon.copland@steptoe-johnson.com  
William J. O'Brien (WV Bar #10549)  
william.obrien@steptoe-johnson.com

**STEPTOE & JOHNSON PLLC**

400 White Oaks Boulevard  
Bridgeport, WV 26330  
Telephone: (304) 933-8000  
Facsimile: (304) 933-8183

*Attorneys for Mylan Inc. and  
Mylan Pharmaceuticals Inc.*

Frank E. Simmerman, Jr. (WVSB# 3403)  
Chad L. Taylor (WVSB# 10564)  
SIMMERMAN LAW OFFICE, PLLC  
254 E. Main St.  
Clarksburg, WV 26301-2170

*Attorneys for Plaintiffs Gilead Sciences,  
Inc. and Emory University*

Upon review, the stipulation is APPROVED and it is so ORDERED.

DATED: \_\_\_\_\_

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IRENE M. KEELEY  
UNITED STATES DISTRICT JUDGE